Public Comment Summary Report

Project Title:

Electronic Specifications for the Core Clinical Data Elements for Risk Adjustment of Hospital-Level Outcome Measures

Dates:

- The Call for Public Comment ran from May 1, 2015 to June 16, 2015.
- The Public Comment Summary was made on June 30th, 2015.

Project Overview:

The Centers for Medicare & Medicaid Services (CMS) has a contract with Yale New Haven Health Services Corporation Center for Outcomes Research & Evaluation (CORE) to develop the core clinical data elements, a set of 21 clinical variables from electronic health records (EHR) that are routinely collected and can be feasibly extracted for use in risk-adjusted hospital-level outcome measures. The contract name is: Development, Reevaluation, and Implementation of Hospital Outcome/Efficiency Measures; Contract Number: HHSM-500-2013-13018I- T0001 Modification 000002. CMS envisions using the core clinical data elements in conjunction with other sources of data, such as administrative claims-based data, to calculate "hybrid" outcome measures. Hybrid outcome measures are hospital quality measures that utilize more than one source of data.

CORE worked with Mathematica Policy Research to electronically specify the core clinical data elements. As part of its measure development process, CMS requested interested parties submit comments on the electronic specifications and value sets for the core clinical data elements. We also asked that comments focus on technical aspects of the electronic specifications as opposed to comments focusing on policy-related issues or concerns associated with the implementation of the core clinical data elements. Specifically, we sought comments on the:

- Ease of electronically extracting these data from an electronic health record (EHR) without the need for manual abstraction;
- Measure logic (i.e., the clarity and specificity of the instructions for obtaining data to be reported); and
- Appropriateness of codes contained in value sets for identifying relevant encounters and first captured clinical data during a clinical encounter.

Project Objectives:

- To create valid and easily interpreted electronic specifications with Quality Data Model (QDM) elements that will facilitate accurate extraction of the core clinical data elements from most currently operating EHRs.

Information About the Comments Received:

- Public comments were solicited by email notifications and announcements made during stakeholder group meetings.
- The request for comments was posted on the CMS Call for Public Comment website. (http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/CallforPublicComment.html)

Fourteen comments were received in total, from 13 submissions through JIRA:

- 3 comments from an EHR vendor (Epic)
- 2 comments from a not-for-profit healthcare system (Partners Healthcare)
- 8 comments from a measure developer (The Joint Commission)
- 1 comment from an independent consult

Stakeholder Comments—General

Summary of general comments

Most comments did not include statements of support or arguments against the electronic specifications, although one commenter expressed support for the intent of the core clinical data elements. Most comments were focused on the hospital arrival component of the specifications. Several comments were related to the value sets of the specifications. A few comments were out of scope for this comment period.

Proposed action: See CMS's responses and proposed actions under the measure-specific comment summaries below.

Measure-Specific Comment Summaries

Encounter Definition

One comment identified an issue in the logic regarding defining the start and end of an encounter, or hospital visit, in the EHR. The core clinical data elements use the start and end of each "encounter" to determine if the outpatient visit (for example, an emergency department visit, or visit to a procedure area such as diagnostic imaging or operating room) led immediately to an inpatient admission (or encounter) that qualifies for the denominator of the specifications. The commenter noted that a stop, or end time for an outpatient visit that precedes an inpatient admission may not correspond to the actual time a patient physically leaves an outpatient area, like the emergency room. The outpatient visit (encounter) may stay open in the EHR to allow clinicians to enter billing information or to update clinical information long after the patient has been admitted to and has arrived on an inpatient hospital unit. The commenter suggested changing the specification logic from "hours from the start of an episode of care" to "hours

before and after the start of the inpatient encounter [or admission],” stating that the latter is a more standard reference point.

Response: We appreciate your comment. We worked within the constraints of the existing standards when developing the timing relationships for the core clinical data elements for encounters that result in an inpatient admission. We will consider your suggestion to use a timeframe prior to the inpatient admission.

Hospital Arrival/Facility Definition

Two comments addressed the concept of hospital arrival time, which is crucial in order to accurately capture the core clinical data elements. The core clinical data elements set the hospital arrival time, the time at which the patient first interacted with the hospital, as the zero start time. One commenter noted that many healthcare networks are groups of facilities. Therefore, determining when the patient arrived at the “facility” could be difficult. Many hospitals have adjacent medical office buildings. In addition, many institutions may have two facilities that are some distance apart but share a billing number. In these cases, and potentially many others, the data element of hospital arrival could be open to interpretation and ambiguous.

Response: We thank you for your comments. The intent of these data elements is to determine a patient’s severity of illness prior to the start of care. Because patients can receive care during an emergency department visit, or in outpatient hospital locations prior to being admitted as an inpatient to the hospital, it is important to capture vital signs and laboratory tests obtained in those settings. We appreciate the suggestion to provide a more precise term than “facility.” We will consider this during field testing of the specifications. We will work with testing sites and consider suggestions from public comment to determine the best way to specify this concept.

Value Sets

Eight comments addressed concerns around the value sets. Specifically, commenters suggested closely reviewing the content of specific value sets to ensure the correct codes within the code systems (SNOMED and LOINC), which define each value set, are captured. Some commenters requested the use of a purpose statement for grouped value sets to indicate the clinical significance of the grouping. Lastly, commenters suggested CMS use a naming convention to improve the clarity and simplicity of the value sets.

Response: We thank you for your comments. The development team will consider adding purpose statements to ensure that the groupings of value sets are consistent with their intent. We will review the value sets for the core clinical data elements and compare them with existing value sets to support harmonization and include appropriate terminologies and codes that reflect the intent of the core clinical data elements.

Transfer Status and Socioeconomic status variables

Two comments expressed support for the use of clinical data to risk adjust quality measures, and asked about the potential inclusion of socioeconomic status variables and transfer status information in the core clinical data elements.

Response: We thank you for your comments expressing your support for the core clinical data elements. With regard to the inclusion of socio-demographic variables and transfer status, these requests are out of the scope of this public comment period, which specifically focuses on the electronic specifications of the currently identified core clinical data elements. CMS will reevaluate decisions regarding the content of the core clinical data elements as advancements in EHR technology and interoperability make data collection for other data elements more feasible in the future.

Health Quality Measures Format (HQMF) readiness

One comment addressed the use of the HQMF format, which is intended for a complete measure, to specify the core clinical data elements for risk-adjustment purposes. The commenter stated that it is confusing to use a numerator/denominator structure for the collection of risk-adjustment variables.

Response: We thank you for your comments on the core clinical data elements. The development team will take this recommendation under consideration.

Preliminary Recommendations

- Continue feasibility testing, specifically around the encounter start time.
- Revise specifications and value sets as needed based on issues raised during the public comment period and from the results of field testing.

Overall Analysis of the Comments and Recommendations

Overall, the comments and feedback received provided useful input into the core clinical data element specifications. Changes to the specifications will be proposed and reviewed once testing is complete.

Table 1. Verbatim Public Comments and Responses

Date posted	Verbatim comment	Commenter	Type of Org.	Recommendations/Actions taken
5/11/2015	The numerator definition is: For patients in the denominator, report the first value for vital signs captured within 2 hours of arrival at the same facility to which the patient is subsequently admitted, and for laboratory test results within 24 hours of arrival. First values for the following data elements are captured in the Emergency Department or outpatient area before a patient is subsequently admitted to the same hospital or on an inpatient unit for directly admitted patients: Hospital arrival is specified as: $HospitalArrival = Union of: "Encounter, Performed: Inpatient encounter CCDE" satisfies all (length of stay <= 365 day(s)) (facility location arrival datetime) "Encounter, Performed: ED Encounter CCDE" satisfies all <= 60 minute(s) ends before or concurrent with start of "Encounter, Performed: Inpatient encounter CCDE (length of stay <= 365 day(s))" (facility location arrival datetime) "Encounter, Performed: Ambulatory" satisfies all	Howard Bregman, MD Epic Corporation	EHR vendor	We thank you for your comments on the core clinical data elements. Stakeholder comments will be reviewed by measure developers and taken under consideration. Responses are provided above.

Date posted	Verbatim comment	Commenter	Type of Org.	Recommendations/Actions taken
	<= 60 minute(s) ends before start of "Encounter, Performed: Inpatient encounter CCDE (length of stay <= 365 day(s))" (facility location arrival datetime) I am concerned regarding the requirement that one encounter "ends" in a certain interval before another begins, as the definition of when an encounter ends is not standardized. As an alternative, can't the measure just look at all data collected within 2 or 8 or 24 hours before the inpatient encounter begins? Wouldn't it be more standard to consider data within a fixed time interval before the inpatient encounter start? These issues will have significant impact on the data. Further clarification: After investigation, we determined that this specification will not work for Epic users given Epic's current data structure, and will probably fail in other EHR's as well. The problem is the above mentioned concern regarding the end of an encounter falling into a certain look back period. Unfortunately, when an encounter ends is not well defined. You might think that it must mean the time when the patient leaves, but in practice it isn't. For billing purposes the encounter ends when the provider closes it for the purposes of billing. This may be days after the patient is discharged. Unfortunately this definition may not be consistent among various kinds of encounters. How to fix this? One way as suggested above is to not deal with different encounters at all, instead start with the time the patient arrives at the inpatient facility, look			

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	back a fixed number of hours, and find the first set of vital signs collected in that time interval. There may be other ways, but these must be investigated and defined before this measure is released.			
5/20/2015	The data elements used don't have consistent names, and the names don't always make sense. Example of inconsistency: • Laboratory Test, Performed: Creatinine Level Lab Test Group • Laboratory Test, Performed: Chloride Lab Test Blood Serum Plasma Moles Per Volume The second name includes the type of specimen (blood serum plasma) and a reference to the units (moles per volume), the first, which is a similar blood test, has none of these. Problem with names that don't make sense: Chloride is measured in serum, which is derived from a blood sample. So it's not clear why the words blood and plasma also are included, as they provide no additional information and are somewhat misleading. Also, the value sets in some cases don't match the name that is given to them. The value set names are similarly inconsistent and confusing.	Howard Bregman, MD Epic Corporation	EHR vendor	We thank you for your comments on the core clinical data elements. Stakeholder comments will be reviewed by measure developers and taken under consideration. Responses are provided above.

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	We suggest to remove all references to specimen and units from the value set name, and just keep the simple language of "level lab test" or similar.			
5/21/2015	The numerator definition is: For patients in the denominator, report the first value for vital signs captured within 2 hours of arrival at the same facility to which the patient is subsequently admitted, and for laboratory test results within 24 hours of arrival. First values for the following data elements are captured in the Emergency Department or outpatient area before a patient is subsequently admitted to the same hospital or on an inpatient unit for directly admitted patients: Hospital arrival is specified as: $HospitalArrival = Union of: "Encounter, Performed: Inpatient encounter CCDE" satisfies all (length of stay <= 365 day(s)) (facility location arrival datetime) "Encounter, Performed: ED Encounter CCDE" satisfies all <= 60 minute(s) ends before or concurrent with start of "Encounter, Performed: Inpatient encounter CCDE (length of stay <= 365 day(s))" (facility location arrival datetime)	Howard Bregman, MD Epic Corporation	EHR vendor	We thank you for your comments on the core clinical data elements. Stakeholder comments will be reviewed by measure developers and taken under consideration. Responses are provided above.

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	"Encounter, Performed: Ambulatory" satisfies all <= 60 minute(s) ends before start of "Encounter, Performed: Inpatient encounter CCDE (length of stay <= 365 day(s))" (facility location arrival datetime) I am concerned that this specification is going to get stymied on the definition of "same facility" and I question why this requirement is necessary. The phrase does not seem to have a precise enough definition to be workable, and if there is a precise definition, I don't see it in the specifications. Remember that enterprise electronic health records cover multiple facilities at multiple sites and collate all the records together, so there is no clear definition of when one facility ends and another begins. Also, the hospital arrival definition does not seem to specify facility at all.			
6/9/2015	Partners Healthcare System is very supportive of the effort by CMS to increasingly use clinical data from electronic health records in performance measurement programs. The evaluation process completed by the Yale New Haven Health Services Corporation was well designed, and we agree with the methodology. We have two important areas where we hope CMS will consider its position: 1) The Technical Expert Panel achieved strong agreement (83%) that patient race and ethnicity were	Thomas Sequist, MD Partners Healthcare	Not-for-profit healthcare system	We thank you for your comments on the core clinical data elements. Stakeholder comments will be reviewed by measure developers and taken under consideration. Responses are provided above.

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	feasible for collection, however were not considered for further testing due to the concern that such risk adjustment may mask racial disparities in care. While the team from Yale has conducted numerous analyses to inform the Hospital Readmissions Reduction Program metrics, there is an increasingly large evidence base demonstrating that race/ethnicity and other markers of socioeconomic status play a large role in predicting readmissions, sometimes as large as significant chronic illnesses including chronic pulmonary disease. We are very supportive of transparency and eliminating health disparities, however we are concerned that the current discussion conflates the concept of promoting health equity with the concept of distribution of performance incentives. Quality measurement programs should be designed to monitor and be transparent around health equity and racial disparities. However, distribution of performance incentives based on relative performance across hospitals needs to ensure that we acknowledge the work being done by hospitals to care for large proportions of underserved populations, and risk adjustment for race/ethnicity is core to achieving that goal. 2) The Technical Expert Panel could not support use of data describing whether patients were transferred from or transferred to another hospital. We agree that the reliability of such data are not high enough to recommend their inclusion in standardized risk adjustment programs. However, we encourage CMS to explore methods of obtaining such information and analyzing its impact on risk adjustment models as the			

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	literature certainly suggests that the characteristics (particularly comorbid conditions) and health outcomes of patients experiencing inter-hospital transfers are different compared to patients receiving their entire course of care at a single institution.			
6/16/2015	For the grouping value sets used in the CCDEs, the "Purpose" information is missing. Please add this information. In grouping value sets it would be appropriate to note that the grouping exists to bring together value sets with the required characteristics. For example, 2.16.840.1.113762.1.4.1104.5 "Blood urea nitrogen serum plasma" grouping value set could have a Clinical Focus "Groups together value sets that include LOINC codes representing Blood Urea Nitrogen laboratory tests with units of either Mass per volume OR Moles per volume."	Rob McClure, MD Independent consultant	Independent consultant	We thank you for your comments on the core clinical data elements. Stakeholder comments will be reviewed by measure developers and taken under consideration. Responses are provided above.
6/16/2015	Some of the CCDE value sets are exact duplicates or close matches to existing, previously developed value sets. Historically, duplicate or similar value sets with equivalent intents have been problematic from implementers. We urge the developers not to create redundant value set content and rely on existing value sets instead, articulating and collaborating with respective stewards as necessary. Examples include inpatient and ambulatory encounters, platelet count, body temperature, diastolic blood pressure and systolic blood pressure.	Rute Martins The Joint Commission	Measure developer	We thank you for your comments on the core clinical data elements. Stakeholder comments will be reviewed by measure developers and taken under consideration. Responses are provided above.

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6/16/2015	While we recognize the developers made their best attempt at specifying the CCDEs within the HQMF, with explicit indication that the file does not represent a measure, the specification of risk factor elements as part of the numerator population is confusing. It is apparent that the representation of simple logic as part of risk factor definition is not currently supported by HQMF, and the intent is to define a cohort (as specified in the initial population and denominator) along with selected instances of certain data elements. We urge the developers and CMS to work with HL7 to make the necessary adjustments to the HQMF standard for an accurate and clear representation of the CCDEs as intended. We strongly recommend that CCDEs are not published for widespread collection before the HQMF standard is adequately developed to support the risk variable logic use case.	Rute Martins The Joint Commission	Measure developer	We thank you for your comments on the core clinical data elements. Stakeholder comments will be reviewed by measure developers and taken under consideration. Responses are provided above.
6/16/2015	Some value sets include both LOINC and SNOMED-CT concepts to define observables (e.g. systolic blood pressure) whereas others focus exclusively on LOINC. As I understand it, the recommended standard terminology for observables would be LOINC, and existing value sets include LOINC codes exclusively (when available). In addition, it is unclear why some value sets include the additional SNOMED-CT observable entities while others do not (e.g. diastolic blood pressure).	Rute Martins The Joint Commission	Measure developer	We thank you for your comments on the core clinical data elements. Stakeholder comments will be reviewed by measure developers and taken under consideration. Responses are provided above.

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6/16/2015	Some value sets are defined as groupings (e.g. glucose blood serum plasma) whereas others are defined as extensional LOINC value sets (e.g. potassium lab test). However, for the latter, multiple related value sets seem to exist which begs the question of why these weren't grouped and used in the CCDEs.	Rute Martins The Joint Commission	Measure developer	We thank you for your comments on the core clinical data elements. Stakeholder comments will be reviewed by measure developers and taken under consideration. Responses are provided above.
6/16/2015	Some value sets including SNOMED-CT observable entities include the qualifier "first" in their name (e.g. first heart rate). However, the value set content does not reflect the intent of this qualifier, which should be removed from the value set name.	Rute Martins The Joint Commission	Measure developer	We thank you for your comments on the core clinical data elements. Stakeholder comments will be reviewed by measure developers and taken under consideration. Responses are provided above.
6/16/2015	Assuming ED stands for emergency department, this value set's content includes concepts that are not aligned with an ED visit (e.g. home visit). The value set seems to need extensive revisions.	Rute Martins The Joint Commission	Measure developer	We thank you for your comments on the core clinical data elements. Stakeholder comments will be reviewed by measure developers and taken under consideration. Responses are provided above.
6/16/2015	It is indicated in the HQMF guidance that the tool intends to support extraction of the first vital signs captured within 2 hours of arrival and lab test results captured within 24 hours of arrival. The $HospitalArrival variable attempts to define the arrival time by establishing relationships between the inpatient encounter and potential preceding encounters and requiring the existence of a facility location arrival datetime, however 1) this QDM attribute has been	Rute Martins The Joint Commission	Measure developer	We thank you for your comments on the core clinical data elements. Stakeholder comments will be reviewed by measure developers and taken under consideration. Responses are provided above.

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	notoriously ill-defined; 2) the existence of the attribute does not require its use in the timing comparisons where the variable is used. It is unclear what location the facility location arrival datetime attribute refers to when no facility location attribute has been defined. In addition, it is unclear how the facility location attribute datetime would be distinct from the encounter start datetime, especially taking into account the definition of arrival described in guidance: "this timing is relative to the time a patient is registered in the electronic system as having arrived, usually by administrative staff". This could very well be the time the encounter is created in the system.			
6/16/2015	The hemoglobin blood serum plasma value set includes some available LOINC codes but not all. It is unclear why some codes were used and not others. We strongly urge the developers to clearly state the rationale for inclusion/exclusion of codes in each value set purpose statement.	Rute Martins The Joint Commission	Measure developer	We thank you for your comments on the core clinical data elements. Stakeholder comments will be reviewed by measure developers and taken under consideration. Responses are provided above.